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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
04/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,714	DEBRUYNE ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-48* is/are pending in the application.

4a) Of the above claim(s) *47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20050527;20070410*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 47 and 48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/23/2009.

2. Applicant's election without traverse of claims 38-46 in the reply filed on 2/23/2009 is acknowledged.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 38-46 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In regards to claim 38, the term "and/or" renders it unclear whether the delivery means need be capable of delivering substance "during and following" implantation, or "during or after" implantation. The Examiner is considering the claim to be limited to delivering "during or after" implantation.

6. In regards to claim 40, "the cochleostomy site" is lacking antecedent basis because not "site" has been set forth in claim 1 and claim 1 does not require that the implant be a cochlear implant.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 38-40 and 42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuzma et al. (US 6,309,410, hereinafter "Kuzma").

9. In regards to claim 38, Kuzma discloses an implantable stimulating device comprising a lead (proximal portion of 10); a resiliently flexible elongate member extending from the lead having at least one electrode (distal portion of 10 and elements 200); a bioactive delivery means (20, see 25' in Fig. 2B) adapted to deliver a bioactive substance at a location spaced from the distal end of the member (Fig. 2A), and wherein the substance delivery means comprises a body having a chamber (lumen 25') and an outlet (col. 6, lines 18-22); and further wherein the body is relatively slidably mounted to the lead of the device (Fig. 2B and col. 4, lines 19-29).

10. In regards to claim 39, the device is a hearing implant electrode assembly (col. 1, lines 15-25).

11. In regards to claim 40, the outlet of the substance delivery means is positionable outside and adjacent a cochleostomy site, for instance, right as the positioner is inserted behind the electrode carrier.

12. In regards to claims 42 and 43, the body of the delivery means comprises an annular member that is positioned around the lead (Fig. 2; the means is annular/around the lead in the plane of the page), and has a second portion (near the center of the cochlea) having an OD less than a first portion (near the entry into the cochlea).

13. In regards to claim 44, Kuzma discloses that the drug delivery channel passes "longitudinally through" (col. 6, lines 3-21) the device, and thus the outlet is in the distal end of the body and the body includes an inlet in the proximal end (Figs. 2A and 2B).

14. In regards to claim 45, Kuzma discloses that the channel may be provided with small openings to leach the drug from the channel (col. 6, lines 13-19).

15. Claims 38-40 and 42-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Kramm et al. (US 6,936,040, hereinafter "Kramm").

16. In regards to claim 38, Kramm discloses an implantable system comprising a lead (proximal portion of 14); a resiliently flexible member extending from the lead and having an electrode (distal end of 14; col. 5, lines 37-39); a bioactive substance delivery means (Fig. 3) adapted to deliver a substance at a location spaced from the distal end of the member during or following implantation (col. 5, lines 37-39; when the lead is "directed out of the distal end" of the catheter); wherein the delivery means comprises a body defining a chamber (56) and an outlet (48) and wherein the body is relatively slidably mounted to the lead (col. 5, lines 37-39).

17. In regards to claims 39 and 40, Kramm's electrode device is inherently capable of being used as a hearing implant electrode assembly and positionable outside and adjacent a cochleostomy site because the claim does not actually require a hearing aid device (i.e., an electrode is capable of passing electrical signals regardless of its intended use), and Kramm's device is of a size capable of being placed in a cochlea because it is of a size capable of placement in the similar-dimensioned coronary vasculature.

18. In regards to claim 42, the body comprises an annular member positioned around the lead (42 and 50).

19. In regards to claim 43, the annular member has a first and second portion having different ODs (42 and 50).

20. In regards to claim 44, the outlet of the body (48) is positioned in the distal end and the body includes an inlet at the proximal end (54).

21. In regards to claim 45, the lumen/chamber acts as a reservoir and the substance leaches from the chamber into the tissue (col. 6, lines 45-50).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claims 41 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma. Kuzma discloses the essential features of the claimed invention except for a "stop" on the lead that prevents the substance delivery means from moving past the stop means; or an outlet that includes a semi-permeable membrane. It is well known in the cochlear stimulation arts to provide stops on leads that prevent positioning devices, such as Kuzma's, from moving past the stop means to provide the predictable result of avoiding damage to the cochlea and ensuring proper placement of the electrodes relative to the positioner; and to provide drug outlets that include semi-permeable membranes to provide the predictable result of releasing drugs at a specifically desired rate. Therefore, it would have been obvious to one having ordinary skill at the time the invention was made to provide Kuzma's invention with a stop on the lead that prevents the positioning device from moving past the stop means to provide the predictable result of avoiding damage to the cochlea and ensuring proper placement of the electrodes relative to the positioner; and to provide a drug outlet that includes a semi-permeable membrane to provide the predictable result of releasing drugs at a specifically desired rate.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kuzma (US 6,321,125) is one of many teachings of providing cochlear electrode carriers with stops and Jolly et al. (US 7,044,942) is one of many teachings of providing drug delivery devices with semi-permeable membranes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/

Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762